K092826 NOV 12 2009

5.0510(k) Summary

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the ASAP® Antibacterial Silver Wound Dressing Gel is provided below.

Device Common Name: Antibacterial Wound Gel

Device Proprietary Name: ASAP® Antibacterial Silver Wound Dressing Gel

Submitter:
American Biotech Labs, LLC
80 West Canyon Crest Road
Alpine, UT 84004

Contact:
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Classification Regulation: Unclassified, pre-amendment

Panel: General & Plastic Surgery

Product Code: FRO

Predicate Devices:
K082333 - ASAP® Wound Dressing Gel

K083103 –AcryDerm Antimicrobial Silver Wound Gel Dressing Model #B

Indication for Use:

ASAP® Silver Antibacterial Wound Dressing Gel is indicated for use in the management of 1st and 2nd degree burns, wounds such as stasis ulcers, pressure ulcers, diabetic ulcers, lacerations, abrasions, skin tears, surgical incision sites, device insertion site wounds, graft sites and donor sites.

Device Description:

ASAP® Silver Antibacterial Wound Dressing Gel is a water based gel wound dressing that contains silver that in laboratory tests has been shown to inhibit the growth of microorganisms such as: *Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli,* antibiotic resistant strains, MRSA and VRE as well as fungi such as *Candida albicans.*

The high moisture content gel contains a base matrix composed of hydrophilic and buffering compounds and contains silver from American Biotech Labs' proprietary silver hydrosol suspension. ASAP® Antibacterial Silver Wound Dressing Gel is supplied in a multi-dose gel pump and a tube (collapsible, low-density polyethylene lined metal tube, sealed on one end and fitted with a pop-open screw cap on the other end).

Technological Characteristics:

The composition of ASAP® Antibacterial Silver Wound Dressing Gel is identical to that for ASAP® Wound Dressing Gel cleared in K082333. No changes have been made the product since previous clearance. Furthermore, the ASAP® Antibacterial Silver Wound Dressing Gel is substantially equivalent to the predicate devices listed above in that silver is the antibacterial ingredient and moisture is managed using an aqueous base combined with a proper blend of hydrophilic substances. ASAP® Antibacterial Silver Wound Dressing Gel contains silver hydrosol that may inhibit the growth of microorganisms within the dressing. The product was evaluated through standard biocompatibility tests (ISO 10993) and found to be acceptable. Antibacterial effectiveness was established through testing with appropriate organisms.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV 12 2009

American Biotech Labs, LLC
% Biologics Consulting Group, Inc.
Ms. Miriam Provost
Senior Consultant
1317 King Street
Alexandria, Virginia 22314

Re: K092826
Trade/Device Name: ASAP® Antibacterial Silver Wound Dressing Gel
Regulation Number: N/A
Regulation Name: N/A
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 10, 2009
Received: September 14, 2009

Dear Ms. Provost:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): __K092826_____

Device Name: The ASAP® Antibacterial Silver Wound Dressing Gel

ASAP® Antibacterial Silver Wound Dressing Gel is indicated for use in the management of 1st and 2nd degree burns, wounds such as stasis ulcers, pressure ulcers, diabetic ulcers, lacerations, abrasions, skin tears, surgical incision sites, device insertion site wounds, graft sites and donor sites.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092826